IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AMARIN PHARMACEUTICALS IRELAND LIMITED, Plaintiff, v. OMTHERA PHARMACEUTICALS, INC. and ASTRAZENECA PHARMACEUTICALS LP, Defendants.	)	REDACTED - PUBLIC VERSION FILED: AUGUST 25, 2014 C.A. No. 14-791-GMS [redacted]

DEFENDANTS' REPLY BRIEF IN SUPPORT OF THEIR MOTION TO DISMISS THE COMPLAINT

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I. INTRODUCTION

Amarin's Opposition (D.I. 13), like its Complaint, fails to establish that its declaratory judgment action presents an issue ripe for judicial decision or that withholding judicial consideration until the actual launch of Epanova™ would cause it any hardship. Because there is no subject matter jurisdiction, Amarin's complaint should be dismissed. Amarin has also provided—and continues to provide—ample reasons for this Court to exercise its discretion to decline to hear the case at this time.

II. ARGUMENT

Defendants' motion to dismiss this action should be granted to avoid an improper advisory opinion. It should also be granted to avoid expending the Court's resources where there was no imminent dispute at the time of the Complaint. Indeed, while Amarin has characterized the alleged dispute as urgent since March 2014—even before FDA approval— Amarin's counsel

[redacted]

This case is also materially different from those upon which Amarin relies. It does not arise under the Hatch-Waxman Act, and any infringement of the asserted method of treatment claims will depend on future acts by third parties that may never occur. Finally, Defendants' motion to dismiss this action also should be granted because Amarin cannot show any harm, let alone an "immediate and substantial" impact, if required to wait until any direct infringement by a third party has occurred.

Defendants have now made multiple overtures to Amarin in an attempt to avoid unnecessary litigation, including an offer to provide advance notice of the launch of Epanova™. Amarin has rejected Defendants' efforts and instead urges a new legal standard for jurisdiction, whereby a dispute need not be imminent at the time of the complaint so long as infringement

might occur anytime in "the two to two and a half year timeframe for this lawsuit to progress[.]" (D.I. 13 at 11.) In light of Amarin's unwillingness to avoid this unnecessary dispute, Defendants respectfully request that this Court exercise its discretion to decline to hear this prematurely filed case.

A. There Is No Imminent Dispute

Amarin contends that there is an imminent dispute, and has been making this assertion since March 2014, even before FDA approval. (*See, e.g.*, C.A. No. 14-279-GMS, D.I. 1, ¶¶ 6, 7, 33.) In this regard, Amarin has specifically represented that "Defendants' argument that launch is not 'imminent,'" is "factually wrong," and "simply untrue." (D.I. 13 at 1, 11.) For support, Amarin asks this Court to improperly consider unsourced hearsay from an unaffiliated insurance company stating that the "launch [of] Epanova™ [will be] in the fourth quarter of 2014." (D.I. 13 at 5; *see also* D.I. 14-2 at 1-2.) However, Amarin's counsel make this representation knowing full well that Defendants' launch is not imminent.

[redacted][1]

Defendants have also offered to provide advance notice of launch. Thus, there was no imminent controversy at the time the Complaint was filed. [redacted] *See, e.g.*, *Matthews Int'l Corp. v. Biosafe Eng'g, LLC*, 695 F.3d 1322, 1329 (Fed. Cir. 2012) (finding lack of requisite immediacy even after products had been sold when future infringement was

[redacted]

uncertain); *Lang v. Pacific Marine & Supply Co., Ltd.*, 895 F.2d 761, 764-65 (Fed. Cir. 1990) (no immediacy when alleged infringing product would not be produced within nine months of Complaint). When "it is unclear when any even arguably infringing activity will occur, [the alleged] dispute [lacks] the immediacy necessary to support the exercise of declaratory judgment jurisdiction." *Matthews*, 695 F.3d at 1329-30.

B. Further Factual Development Is Required

Contrary to Amarin's assertions, further factual development in this case is required before any dispute can be established or adjudicated. For this additional reason, the action is not ripe and not fit for an anticipatory declaratory judgment opinion. *Cities Serv. Co. v. Dep't of Energy*, 520 F. Supp. 1132, 1139 (D. Del. 1981) ("A particular case is ripe in the constitutional sense if the requisite injury is in sharp enough focus and the adverseness of the parties concrete enough to permit a court to decide a real controversy and not a set of hypothetical possibilities." (internal quotation omitted)).

First, Amarin wrongly analogizes the present case to the facts of *Caraco Pharm. Labs., Ltd. v. Forest Labs., Inc.*, 527 F.3d 1278 (Fed. Cir. 2008), going so far as to state that "[t]his is the same situation." (D.I. 13 at 12.) *Caraco*, however, is distinguishable at least because it arose under the Hatch-Waxman Act, which expressly "create[s] an *artificial act* of infringement for purposes of establishing jurisdiction in the federal courts." *Id.* at 1283 (emphasis in original) (citations omitted). *Caraco* does not suggest, as does Amarin, that the mere submission of a drug application to the FDA necessarily satisfies the first prong of ripeness "in the pharmaceutical context." (*See* D.I. 13 at 11-12.)

To the contrary, *Caraco* was expressly limited to a situation where "no additional facts [were] required to determine whether this drug product infringes the claims" and the claims at issue were to compositions and methods of manufacture. *Caraco*, 527 F.3d at 1295. In the

controlling Hatch-Waxman context, those claims were necessarily infringed, without consideration of any future facts, given the product's ANDA specification. *See Sunovion Pharms., Inc. v. Teva Pharms. USA Inc.*, 731 F.3d 1271, 1280 (Fed. Cir. 2013) ("[I]f an ANDA specification defines a compound such that it meets the limitations of an asserted claim, then there is almost never a genuine issue of material fact that the claim is infringed.").

In contrast to the facts in *Caraco*, the present case does not arise under the Hatch-Waxman Act. Thus, a hypothetical infringement under 35 U.S.C. § 271(e) cannot form the basis of a justiciable controversy here; the facts must do so. *See Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1356 (Fed. Cir. 2003) (finding that when the provisions of 35 U.S.C. § 271(e) are inapplicable, "the plaintiff must prove that the defendant's manufacture, use, or sale of the drug would nonetheless infringe…under a traditional infringement analysis").

Furthermore, the asserted claims in this case are directed to methods of treatment – not compositions of matter or methods of manufacture. (D.I. 1-1 at col. 25, l. 34 – col. 26, l. 45 (claims 1-16 of the '662 patent).) Unlike *Caraco,* the asserted claims here simply cannot be infringed until a series of factual preconditions comes to pass:

- First, Epanova™ must be launched commercially.
- Second, Epanova™ must be prescribed by a physician to a patient "with triglycerides of at least 500 mg/dl."
- Third, Epanova™ must be used by the patient "for a period effective to reduce triglycerides in the subject."
- Fourth, the treatment must not have "increas[ed] LDL-C by more than 20%."

Id. It is presently unknowable if and/or when these factual preconditions will occur.

For example, Table 2 from the Epanova™ label upon which Amarin relies (*e.g.*, D.I. 13 at 6) indicates that the subjects in the referenced study had an LDL-C increase of greater than 21% (2 gram dose) or 26% (4 gram dose) relative to baseline, whereas the asserted claim requires that treatment not "increas[e] LDL-C by more than 20%." (D.I. 1-4 at 4 (Epanova™ label, Table 2); D.I. 1-1 at col. 25, ll. 42-43 ('662 patent claim 1).) In other words, even as framed by Amarin, whether a particular future patient will ever meet the limitations of these method claims is presently unknowable.

The alleged dispute is not ripe unless and until Amarin establishes that treatment with Epanova™ administered to a requisite subject for a period effective to reduce triglycerides in that subject did not increase LDL-C by more than 20%. Since Amarin cannot do so at this time, the Court will have an incomplete factual record to evaluate the alleged dispute. *Ohio Forestry Ass'n, Inc. v. Sierra Club*, 523 U.S. 726, 736-37 (1998) (finding that "further factual development" would avoid "time-consuming judicial consideration of the details" in a case before it was ripe).[2]

Second, while Amarin simultaneously relies on and attempts to distinguish *Matthews* (D.I. 13 at 12-13), that case clearly supports dismissal of Amarin's declaratory judgment action. As characterized by Amarin, *Matthews* "involved a product which could be operated using parameters which did not infringe the method patents at issue, and there was no indication that the customers used the product in an infringing manner." (*Id.* at 13.) The same is true here, for reasons noted above. Furthermore, *Matthews*' accused product had already been sold

[2] Amarin's reliance on *Glaxo* is likewise inapposite. The issue regarding declaratory judgment in *Glaxo* was whether the product described in Novopharm's ANDA would contain Form 2 ranitidine hydrochloride such that Glaxo's claims to a process for the preparation of Form 2 would be infringed. *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1570 (Fed. Cir. 1997). Thus, unlike the present situation, no additional facts needed to be developed.

commercially at the time of the complaint. Here, Amarin's allegations of induced and contributory infringement are even less imminent since Defendants' product in this case has not even launched.

The court's reasons for dismissing the declaratory judgment action in *Matthews* thus apply equally here. *Matthews*, 695 F.3d at 1328 ("[T]here is no evidence as to when, if ever, the [Defendant's] equipment will be used in a manner that could potentially infringe the Method Patents. Matthews has taken no steps toward direct infringement of those patents... [Defendant] does not practice any of the methods disclosed in the Method Patents, and cannot, therefore, be held liable for direct infringement." (citations omitted)). Indeed, here, just like in *Matthews*, future factual preconditions must occur before there could be any ripe claim for inducement or contributory infringement of the asserted method claims. *See id.* at 1329-30.

C. Amarin Cannot Show Any Harm, Let Alone "Immediate and Substantial Impact"

Amarin has yet to allege facts evidencing <u>any</u> impact of delaying litigation until jurisdiction may be proper, let alone an "immediate and substantial" impact as required for an action to be ripe. *Caraco*, 527 F.3d at 1295. Indeed, Amarin had no answer to the Court's question to this effect during the June 16, 2014, teleconference in the prior case. (D.I. 10-1 at 10, ll. 12-15 ("[W]hat is the difficulty that you [Amarin] confront in waiting till launch or otherwise letting us make sure that, in point of fact, the Court does have subject matter jurisdiction?").) Amarin's Opposition is no more illuminating. It contains only bare assertions that Amarin will somehow be "irreparably harm[ed]," that Defendants have "damaged its ability to compete in the omega-3 fatty acid market," and that "[f]urther delay will further damage Amarin." (D.I. 13 at

13.) These unsupported, conclusory assertions are not facts that can establish jurisdiction.[3] *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) ("Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice."). While Amarin's Opposition contends for the first time that it "will seek an injunction… for Defendants' infringement" (D.I. 13 at 13), this is inconsistent with its Complaint, where no such relief was requested. Indeed, given that the asserted patent here does not cover Amarin's own commercial product, the only tangible relief Amarin seeks (or can seek) is an award of monetary damages that it fully acknowledges would only be available "*following* the launch of Epanova™." (D.I. 1 at 8 (emphasis added).)

Since Amarin can show no immediate and substantial impact on its business for purposes of a ripeness inquiry, it proposes a new legal standard for immediacy. Amarin contends it will suffer "immediate" impact for the sake of an Article III controversy if Epanova™ launches anytime within the "two to two and a half year" alleged duration of this lawsuit. (D.I. 13 at 5, 11.) Of course, the problem for Amarin is that the Constitution requires the case to have been ripe on June 20, 2014, when the Complaint was filed – not at some indefinite time in the future. Indeed, Federal Circuit precedent has found no immediacy within much shorter timeframes. *See, e.g.*, *Matthews*, 695 F.3d at 1329 (finding lack of requisite immediacy even after products had been sold when future infringement was uncertain); *see also Lang*, 895 F.2d at 764-65 (no immediacy when alleged infringing product would not be produced within nine months of

[3] Amarin's unsupported assertions that delay somehow "damaged its ability to compete in the omega-3 fatty acid market" (D.I. 13 at 13) also carry no weight, especially as they go beyond and are unsupported by any facts alleged in the Complaint. They constitute no more than mere attorney argument, which this Court and many others have recognized is "no substitute for evidence." *Finjan, Inc. v. Symantec Corp.*, C.A. No. 10-cv-593-GMS, 2013 WL 5302560 (D. Del. Sept. 19, 2013). Mere attorney argument cannot assist Amarin in carrying its burden to prove that jurisdiction was proper when the case was filed.

Complaint). With Amarin having shown no immediate and substantial impact, Amarin's declaratory judgment action fails the Article III ripeness requirement, and should be dismissed.

D. Declining to Hear This Case is the Best Use of This Court's Resources

Jurisdiction afforded by the Declaratory Judgment Act, 28 U.S.C. § 2201, is discretionary. Amarin's unwillingness to fulfill its responsibilities as a declaratory plaintiff—to ensure proper jurisdiction before filing its multiple complaints and rejecting offers to avoid unnecessary motion practice—is further good cause for denying this discretionary jurisdiction.

While Amarin conceded to the Court that "[w]e don't want to be going along in a case that you think there is defective subject matter jurisdiction," (D.I. 10-1 at 8, ll. 10-12) it now contends that Defendants' efforts to avoid defective jurisdiction constitute "needless motion practice." (D.I. 13 at 16.) However, while Defendants have sought to avoid motion practice by disclosing confidential business information to Amarin's counsel and agreeing to provide notice before launch, Amarin has rejected these overtures and instead threatened sanctions. (D.I. 10-3 at 1-2.) Amarin has relentlessly sought to "move the case along more quickly" (D.I. 13 at 8, 16) despite no statutory reason for doing so, such as a Hatch-Waxman 30-month stay, or evidence that they or any other party would be harmed by waiting.

The Supreme Court has stated that Congress' purpose in enacting the Declaratory Judgment act was to create "an opportunity, rather than a duty, to grant a new form of relief to qualifying litigants." *Wilton v. Seven Falls Co.*, 515 U.S. 277, 288 (1995). That opportunity must yield when litigants do not qualify, and when "considerations of practicality and wise judicial administration" prevail. *Id.* Until Epanova™ is prescribed to a patient, ingested, and that patient is monitored for triglyceride and LDL-C changes, there can be no direct infringement and there will be little—certainly insufficient—discoverable evidence. To be sure, courts may render opinions on future infringement. But those are the rare cases outside the Hatch-Waxman

context, where a composition claim or a method of making claim is clearly and necessarily infringed by a pharmaceutical product and adjudication is necessary to avoid immediate and substantial harm. *Caraco*, 527 F.3d at 1296-97. For the asserted method claims of the '662 patent, however, any opinion rendered by this Court on indirect infringement before an accused product launches would be an unnecessary advisory opinion based on an insufficient factual record.

Thus, independent of whether jurisdiction may be found proper in this case, Defendants respectfully request that the Court decline to hear the case at this time under the discretion afforded it by statute and case law precedent.

III. CONCLUSION

Amarin's Complaint is not ripe for adjudication. [redacted] Accordingly, Defendants respectfully request that the Court grant Defendants' motion to dismiss, or alternatively, decline to hear this case, given that Amarin has not established jurisdiction or any legitimate reason to impose the burdens of litigating on this Court and Defendants where the alleged dispute remains premature at best.

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CERTIFICATE OF SERVICE

I, Daniel M. Silver, hereby certify that on August 18, 2014, I caused a true and correct copy of Defendants' Reply Brief in Support of their Motion to Dismiss the Complaint to be served via email on the following counsel of record:

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